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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,224	10/14/2005	Robert C. Giles	13361 PCT US	9719
<div>23719      7590      12/12/2007</div> <div>KALOW &amp; SPRINGUT LLP 488 MADISON AVENUE 19TH FLOOR NEW YORK, NY 10022</div>				
<div>EXAMINER</div> <div>SHAW, AMANDA MARIE</div>				
<div>ART UNIT      PAPER NUMBER</div> <div>1634</div>				
<div>MAIL DATE      DELIVERY MODE</div> <div>12/12/2007      PAPER</div>				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/519,224

**Applicant(s)**

GILES ET AL.

**Examiner**

Amanda M. Shaw

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/22/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group IV (Claims 21-31) in the reply filed on October 1, 2007 is acknowledged. The traversal is on the ground(s) that the Applicants believe that the Examiner has not met the burden of showing that the panels and method of using the panels are independent and distinct. The Applicants further argue that the Examiner would almost certainly cite the same reference in one group against the other group. Applicants also submit that separate searches for each of the alleged groups would be substantially duplicative, and the Examiner has not demonstrated that a search directed to one group is unreasonable or would present an undue burden on the U.S. Patent Office. This is not found persuasive because in the instant case the product as claimed (the SNP panel) can be used in a materially different process. The specification (page 9) defines a "panel" as a pre selected group of SNPs. In the instant case a panel is being interpreted as a group of oligonucleotides wherein each oligonucleotide has a SNP. These oligonucleotides which make up the panel can be used in materially different processes such as for synthesizing primers and probes. Thus restriction for examination purposes as indicated is proper because the SNP panel is distinct from the claimed methods for the reason given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply: (a) the inventions have acquired a separate status in the art in view of their different classification; (b) the inventions have acquired a

separate status in the art due to their recognized divergent subject matter; (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (d) the prior art applicable to one invention would not likely be applicable to another invention; (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. **The requirement is still deemed proper and is therefore made FINAL.**

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-25 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilll (Int J Legal Med Pub 4/2001).

Regarding Claims 21 and 22 Gilll teaches a method wherein a blood stain from a crime scene was analyzed (page 205, col 1). In the instant case the blood stain is being interpreted as a sample of compromised nucleic acids because the specification (page 11) defines a compromised nucleic acid sample as a sample known to contain or suspected to contain nucleic acids wherein the nucleic acids of the sample are too degraded, and dried blood stains are reasonably suspected to contain degraded DNA. Thus Gilll teaches a method of obtaining a sample of compromised nucleic acids. Gilll

further teaches that the sample was genotyped using an array of biallelics (SNPs), wherein the array can comprise up to several hundred loci (page 204, col 2), therefore this array would be able to identify two or more SNPs in the sample. Gilll also teaches comparing the identity of the SNPs in the compromised sample with a panel comprising two or more SNPs. For example in instances when the contributors to the sample are a suspect and an unknown individual, Gilll teaches that the genotype of the sample can be compared to the genotype of the suspect and to the genotype of the unknown (page 205, col 1). Further these SNPs are not genetically linked with respect to one another (since he discloses several hundred loci) and are located outside of tandem repeat nucleic acid sequences. It can be inferred that these SNPs are not STR since Gilll distinguishes SNPs from STR (page 204).

Regarding Claim 23 Gilll teaches a genotyping method wherein the single nucleotide polymorphisms are biallelic (page 204, col 2). Gilll does not specifically state that the alleles of the SNPS are T and/or C, however if several hundred loci are typed it is inherent that some alleles will be T alleles and some will be C alleles.

Regarding Claims 24 and 25 Gill discloses a method of analyzing SNPs for forensic purposes. Gill discloses an example of a typical rape case wherein the mixture comprises contributions from the victim and the suspect (page 206, col 2). Thus Gill teaches a method wherein the population of interest is human and wherein the sample comprises human nucleic acids.

Regarding Claims 27- 28 Gill teaches a method wherein the two or more single nucleotide polymorphisms present in the compromised nucleic acid sample are

identified using an array. In the instant case arrays are considered to be multiplexed reactions since the array format allows for several loci to be examined at once.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Shultz (US Patent 6235480 Issues 5/2001).

The teachings of Gill are presented above.

Gill does not teach a method wherein the SNPs in the sample are identified using a single base primer extension reaction.

However Shultz teaches that single base extension is a technique that allows the detection of SNPs by hybridizing a single strand DNA probe to a captured DNA target. Once hybridized the single strand probe is extended by a single base with labeled dideoxynucleotides which can be detected (column 4, lines 5-12).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by detecting the SNPs using a single base primer extension reaction as suggested by Shultz. Using single base extension reactions as a method to detect SNPs was routinely used in the art at the time of the invention as demonstrated by Shultz. Thus one of skill in the art could have combined the methods of Gill and Shultz, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention.

5. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Koster (US Patent 6133436 Issued 10/2000).

The teachings of Gill are presented above.

Gill does not teach a method wherein the array is an addressable array or a virtual array.

However Koster teaches arrays that are addressable (Col 9, line 45-54). Koster also teaches beads linked to solid supports (Abstract). In the instant case this is being interpreted as a virtual array since the specification (page 29) defines a virtual array as a suspension of microspheres.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using an addressable array as suggested by Koster for the benefit of being able to tell the identity of each nucleic acid on the array based on its location. Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by using a virtual array as suggested by Koster because these arrays compared to flat arrays provide an increased surface area for immobilization of nucleic acids (abstract). In the instant case each of the claim limitations were known, thus one of skill in the art could have combined the methods of Gill and Koster, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of invention.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (Int J Legal Med Pub 4/2001) in view of Jehaes (Int J Legal Med Pub 12/2001).

The teachings of Gill are presented above.

Gill does not teach a method wherein the compromised nucleic acid sample is amplified to a length of from about 10 nucleotides to about 100 nucleotides.

However Jehaes teaches when analyzing forensic DNA samples they found that by selecting primers which amplified short fragments, they were able to detect polymorphisms which were undetected using primers which amplified longer fragments. This was attributed to DNA degradation that occurred after sampling (Abstract). Jehaes concludes that the use of short PCR fragments <200 bp (which encompasses fragments

between 10 and 100 bp) in all forensic cases should improve DNA analysis and increase the success rate of analysis (page 140, col 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gill by amplifying the compromised nucleic acid sample to produce short fragments as suggested by Jehaes for the benefit of being able to detect polymorphisms that were undetectable using longer fragments due to DNA degradation of the sample.

### ***Conclusion***

7. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
Art Unit 1634

  
JULIET C. SWITZER  
PRIMARY EXAMINER